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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,498	10/15/2001	Adrian Clausell	2055-181	4848

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PATENT LEGAL DEPARTMENT/A-42-C
BECKMAN COULTER, INC.
4300 N. HARBOR BOULEVARD
BOX 3100
FULLERTON, CA 92834-3100

EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,498

Applicant(s)

CLAUSELL ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-95 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-95 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: .

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DETAILED ACTION

Claims 1-95 are presented for examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to a method of enhancing uptake of molecules into live cells, classified in class 435, numerous subclasses, including subclass 455.
- II. Claims 5-55, drawn to a method of assaying a cell for enzyme activity, classified in class 435, numerous subclasses, including subclass 18.
- III. Claims 56-95, drawn to an enzyme substrate-containing reagent, classified in a variety of different classes, for example class 530, and numerous subclasses therein, including subclass 353, as well as class 536, subclass 22.1.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are independent and distinct because they recite different processes. Group I recites enhancement of the uptake of any molecule into the cell, whereas Group II recites an enzyme assay method. Thus, the two groups are clearly

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distinct in that they require different steps to be performed. Moreover, a reference which would anticipate one group would not necessarily anticipate or render obvious the other group. Also, both groups recite numerous embodiments requiring extensive searching in numerous different subclasses, clearly constituting a significant burden on the examination process.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products, all of which contain enzyme substrates, can be used in materially different processes, such as enzymatic syntheses of compounds, processes clearly distinct from the cell uptake-enhancing methods recited in the claims.

Inventions II and III are also related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product

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(MPEP § 806.05(h)). As discussed above with respect to the restriction between groups I and III, the claimed products all contain enzyme substrates, and can therefore be used in processes materially different from the claimed assay processes, such as enzymatic syntheses of compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

- (a) the uptake-enhancing agents recited in claim 2;
- (b) the molecules recited in claim 4;
- (c) the enzymes recited in claims 6-8 and 38-40;
- (d) the uptake-enhancing agents recited in claim 15;
- (e) the indicator moieties recited in claim 47;
- (f) the enzymes recited in claims 57-59 and 86;
- (g) the uptake-enhancing agents recited in claim 63;
- (h) the indicator moieties recited in claim 89.

If applicant elects group I, as set forth above, applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of from each of (a) and (b) set forth above,

for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

If applicant elects group II, as set forth above, applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of from each of (c), (d) and (e) set forth above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 5 is generic.

If applicant elects group III, as set forth above, applicant is further required under 35 U.S.C. 121 to elect a **single** disclosed species of from each of (f), (g) and (h) set forth above, for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Thus, a properly responsive election would appear as follows: --

Applicant hereby elects, with traverse, group I, claims 1-4, drawn to a method of enhancing uptake of molecules into live cells. Applicant also elects, with traverse, glycerol as the uptake-enhancing agent of species (a), and nucleic acid as the molecule of species (b).

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

1. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
May 6, 2003